EFFECTIVE DATE NOTE: At 80 FR 29904, May 22, 2015, §640.27 was removed, effective May 23, 2016.

Subpart D—Plasma

§ 640.30 Plasma.

(a) *Proper name and definition.* The proper name of this component is Plasma. The component is defined as:

(1) The fluid portion of one unit of human blood intended for intravenous use which is collected in a closed system, stabilized against clotting, and separated from the red cells; or

(2) The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.

(b) *Source.* (1) Plasma shall be obtained by separating plasma from blood collected from blood donors or by plasmapheresis.

(2) Plasma may be obtained from a unit of Whole Blood collected by another licensed establishment.

[42 FR 59878, Nov. 22, 1977; 48 FR 13026, Mar. 29, 1983, as amended at 50 FR 4139, Jan. 29, 1985; 72 FR 45888, Aug. 16, 2007]

§ 640.31 Suitability of donors.

(a) Whole blood donors shall meet the criteria for donor suitability prescribed in §640.3.

(b) Plasmapheresis donors shall meet the criteria for donor suitability prescribed in §640.63, excluding the phrase ''other than malaria'' in paragraph (c)(9) of that section. Informed consent shall be required as prescribed in §640.61.

[42 FR 59878, Nov. 22, 1977, as amended at 64 FR 45372, Aug. 19, 1999]

EFFECTIVE DATE NOTE: At 80 FR 29904, May 22, 2015, §640.31 was revised, effective May 23, 2016. For the convenience of the user, the revised text is set forth as follows:

§ 640.31 Eligibility of donors.

(a) Whole Blood donors must meet the criteria for donor eligibility prescribed in §§630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§630.10 and 630.15 of this chapter.

§ 640.32 Collection of source material.

(a) Whole Blood must be collected, transported, and stored as prescribed in §640.4. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, until the plasma is removed, the whole blood must be maintained at a temperature between 1 and 6 °C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluations and Research. Whole blood intended for Platelet Rich Plasma must be maintained as prescribed in §640.24 until the plasma is removed. The red blood cells must be placed in storage at a temperature between 1 and 6 °C immediately after the plasma is separated.

(b) Plasma obtained by plasmapheresis shall be collected as prescribed in §§640.62, 640.64 (except that paragraph (c)(3) of §640.64 shall not apply), and §640.65.

[42 FR 59878, Nov. 22, 1977, as amended at 45 FR 27927, Apr. 25, 1980; 50 FR 4139, Jan. 29, 1985; 64 FR 45372, Aug. 19, 1999; 72 FR 45888, Aug. 16, 2007]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, §640.32(b) was amended by removing ''§§640.62, 640.64,'' and adding in its place ''§640.64'', effective May 23, 2016.

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in §610.40 of this chapter and §640.5 (a), (b), and (c).

(b) Manufacturers of Plasma collected by plasmapheresis shall have testing and recordkeeping responsibilities equivalent to those prescribed in §§640.71 and 640.72.

[42 FR 59878, Nov. 22, 1977, as amended at 44 FR 17658, Mar. 23, 1979; 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 66 FR 31165, June 11, 2001]

EFFECTIVE DATE NOTE: At 80 FR 29905, May 22, 2015, §640.33(a) was amended by removing ''§640.5(a), (b),'' and adding in its place ''§640.5(b)'', effective May 23, 2016.

§ 640.34 Processing.

(a) *Plasma.* Plasma shall be separated from the red blood cells and shall be stored at −18 °C or colder within 6